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**Bachman et al.**

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(54) **DEVICES, SYSTEMS AND METHODS FOR ENCLOSING AN ANATOMICAL OPENING**

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***A61B 17/12*** (2006.01)

(52) **U.S. Cl.**
CPC ..... ***A61B 17/12118*** (2013.01)

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USPC ..... 606/108, 191, 200, 213; 623/1.11, 1.13
See application file for complete search history.

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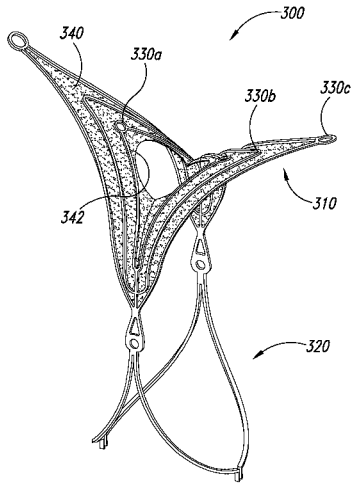
(57) **ABSTRACT**

The present technology is directed generally to devices, systems, and methods for enclosing anatomical openings. In several embodiments, an aneurysm device is endovascularly deliverable to a site proximate to an arterial aneurysm. The aneurysm device includes a closure structure having a distal-facing aspect configured to at least partially occlude the aneurysm and a proximal-facing aspect configured to arch over lumina of an artery. The device further includes a supplemental stabilizer connected to the closure structure and configured to reside in the artery and press outward against a luminal wall thereof. In some embodiments, the device can also include a barrier spanning at least a portion of the distal-facing aspect of the closure structure and configured to further occlude a neck of the aneurysm. In further embodiments, the closure structure can be configured to restrict and/or divert flow to or from the aneurysm.

**9 Claims, 16 Drawing Sheets**



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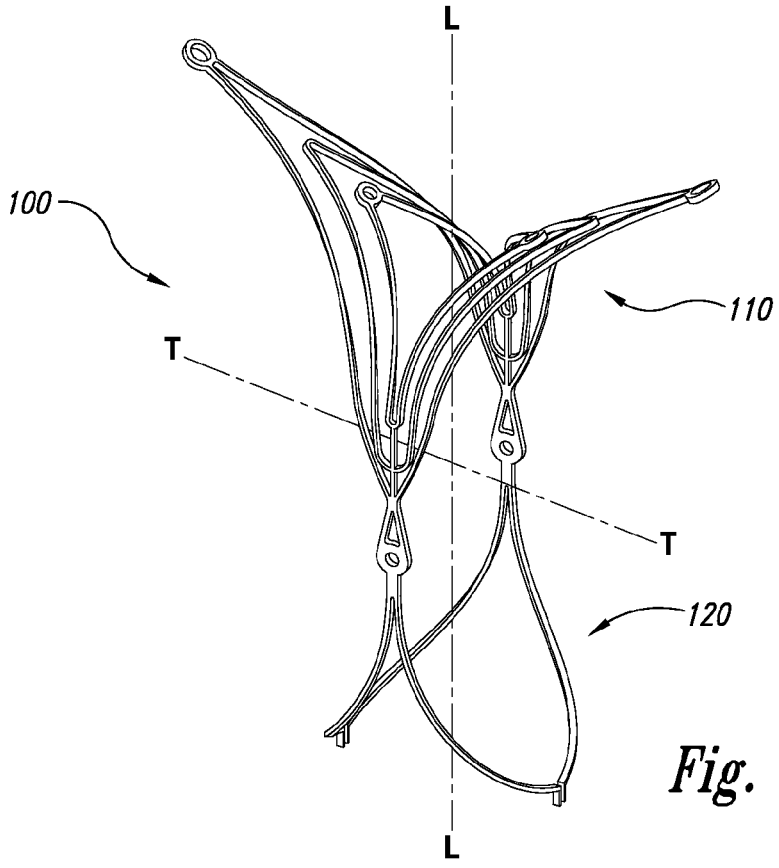
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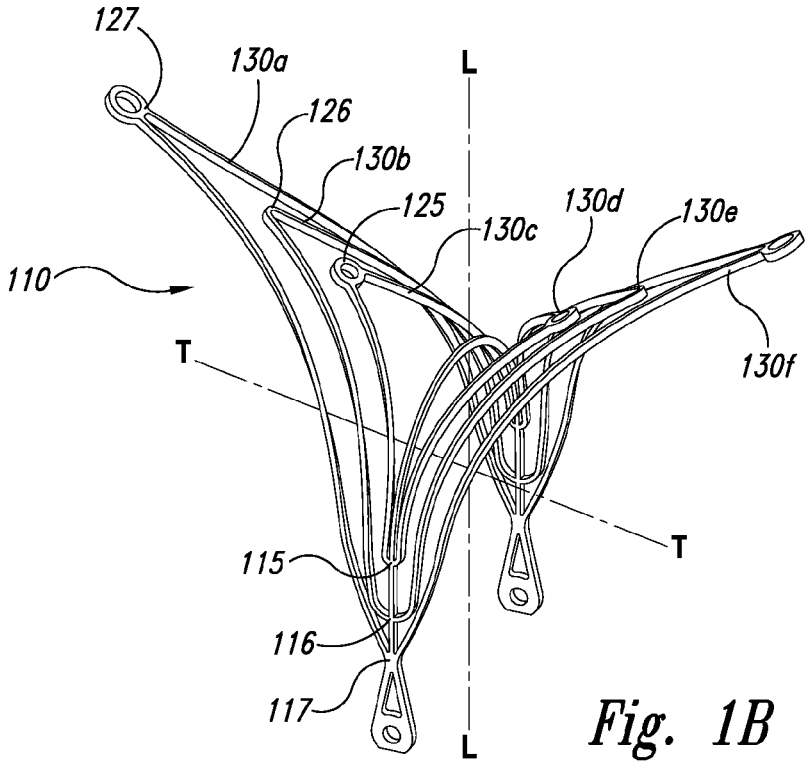
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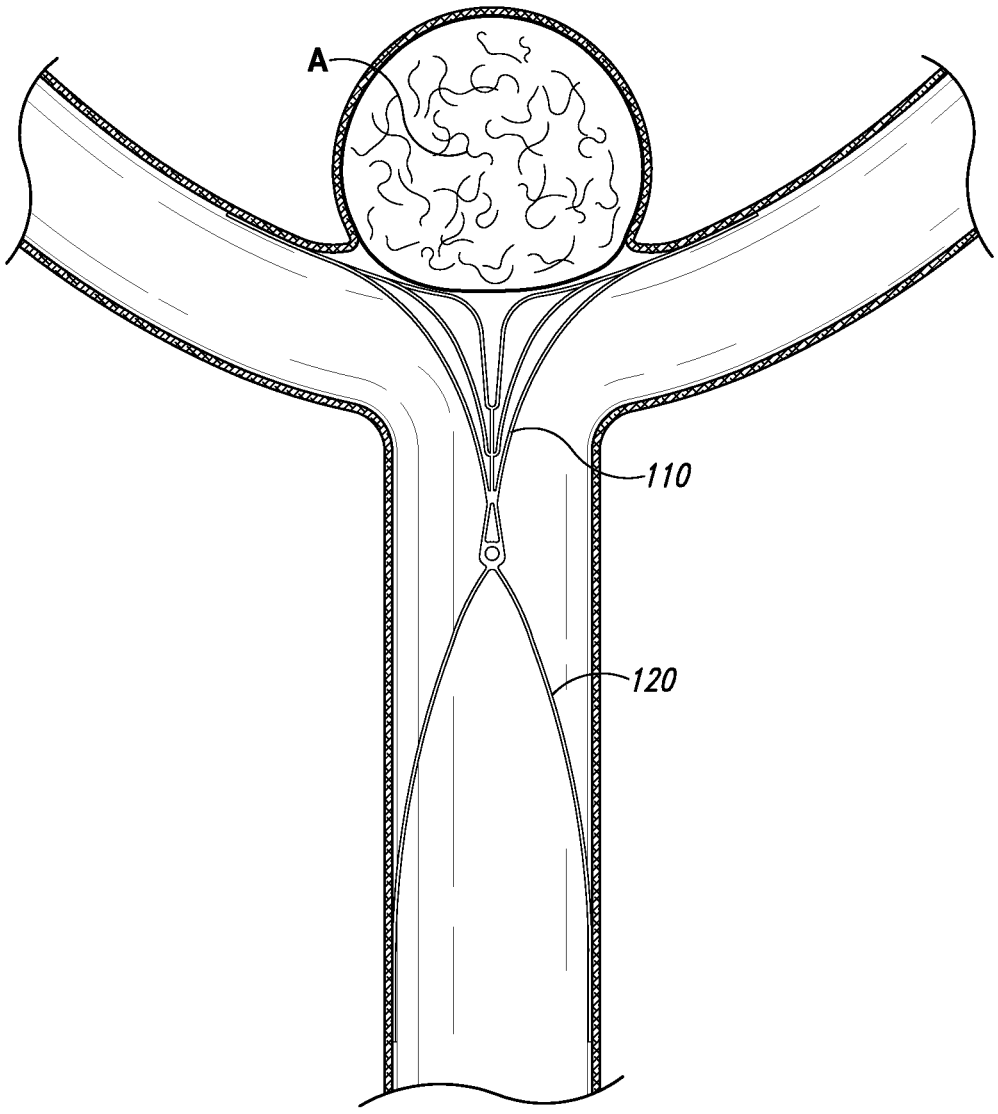


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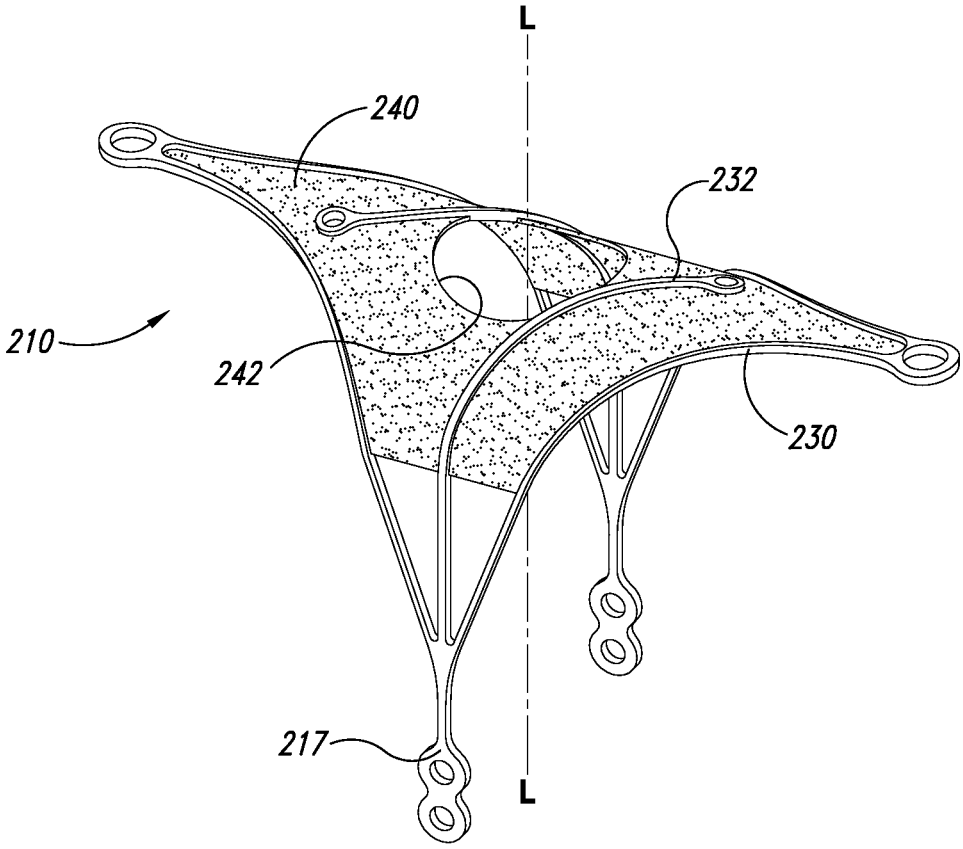


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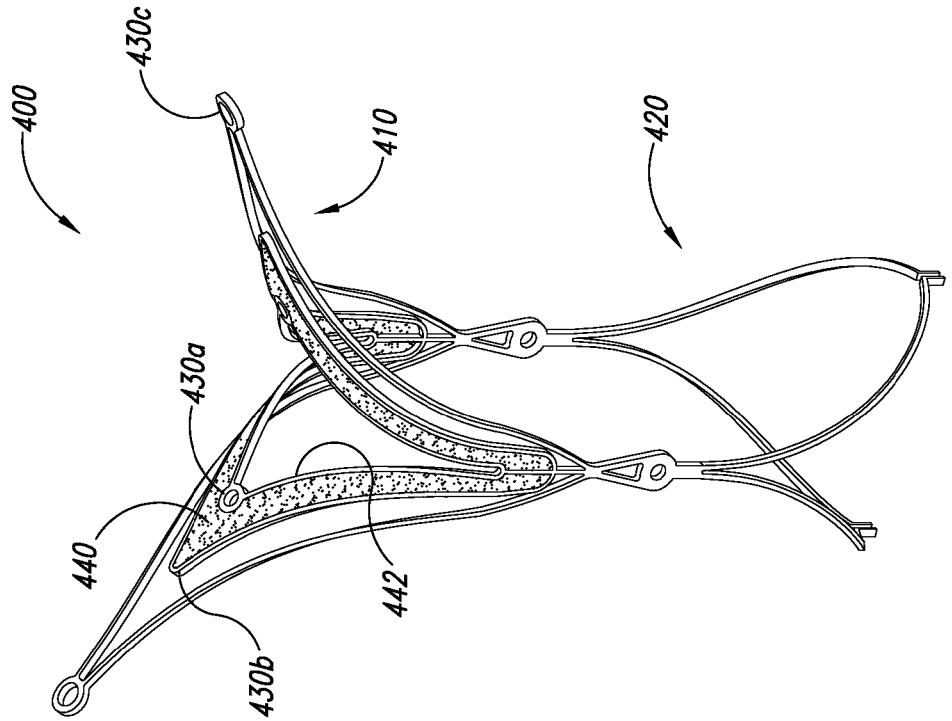
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Fig. 4

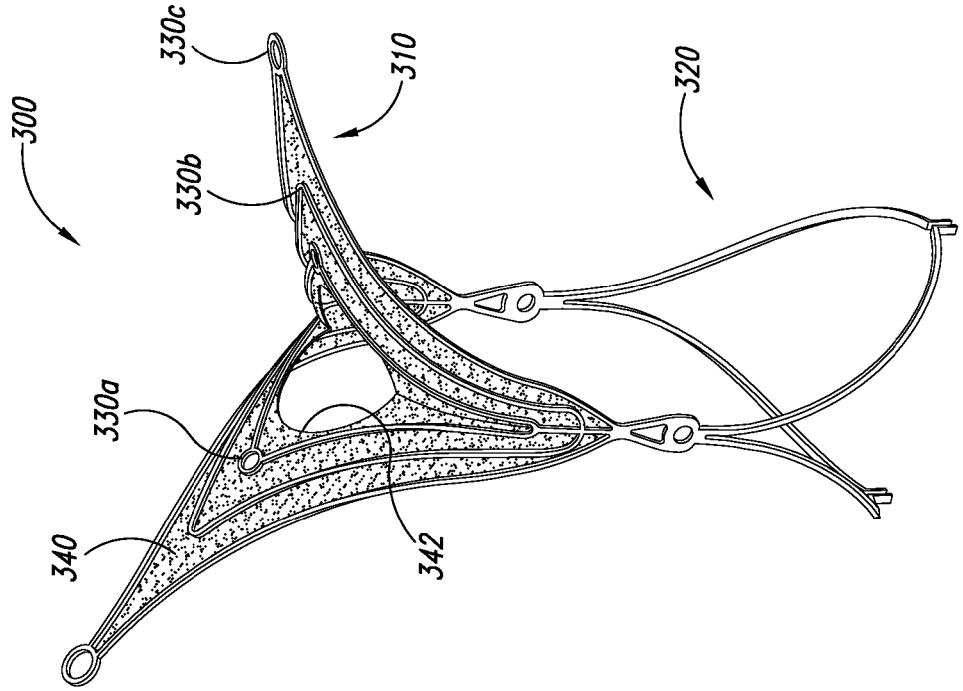
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Fig. 3

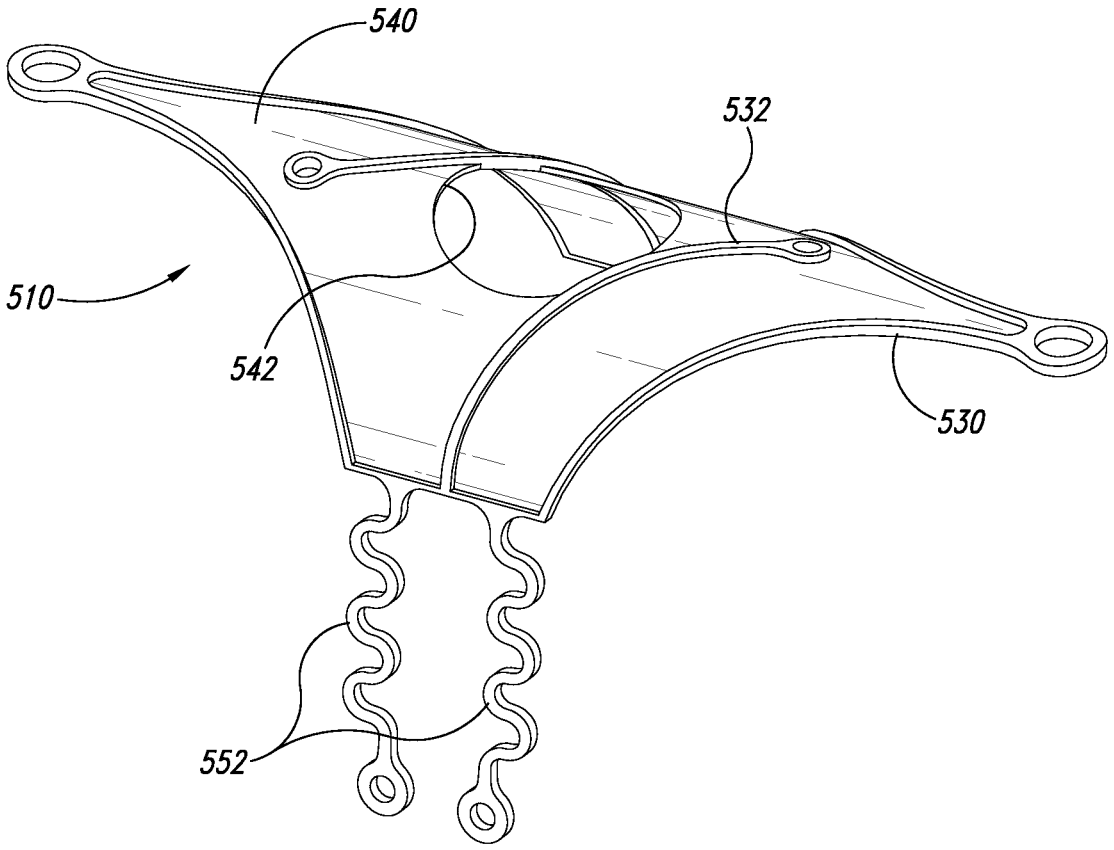


*Fig. 5*

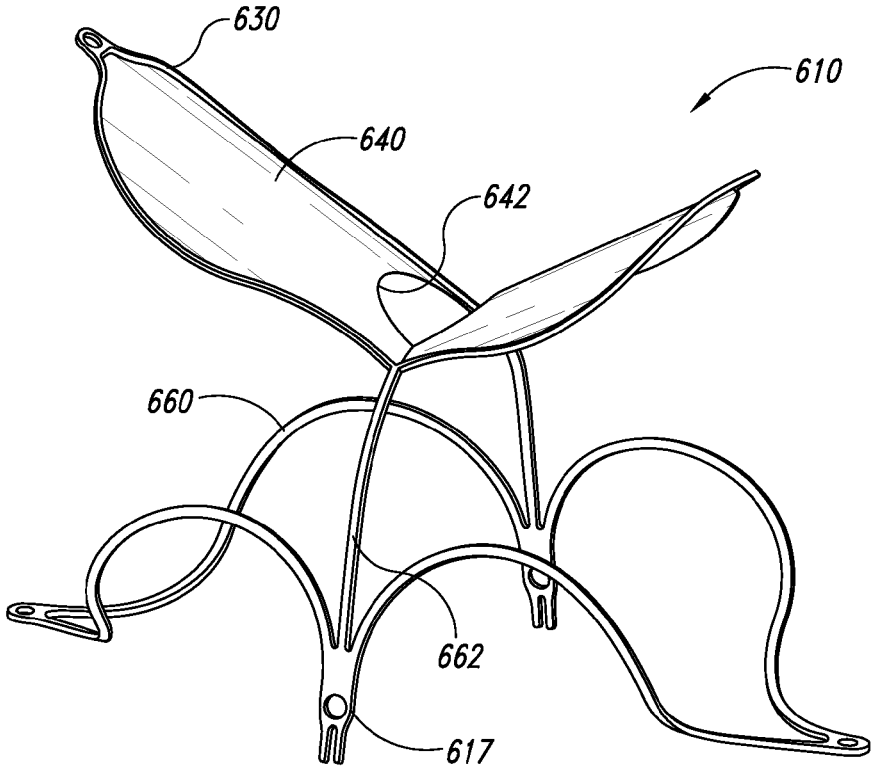


Fig. 6A

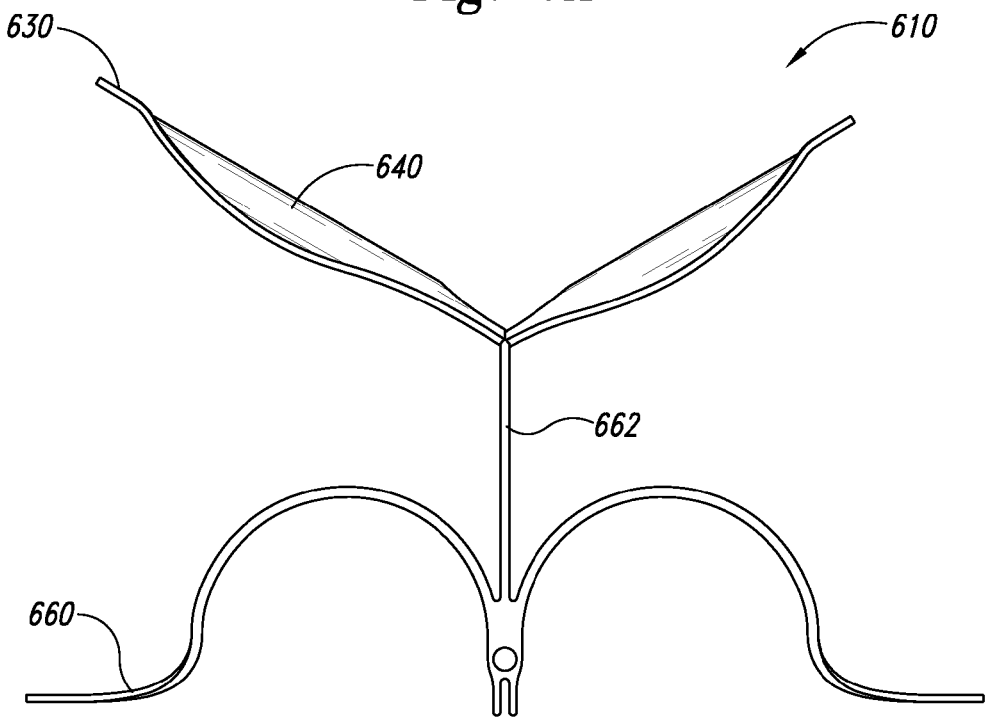


Fig. 6B

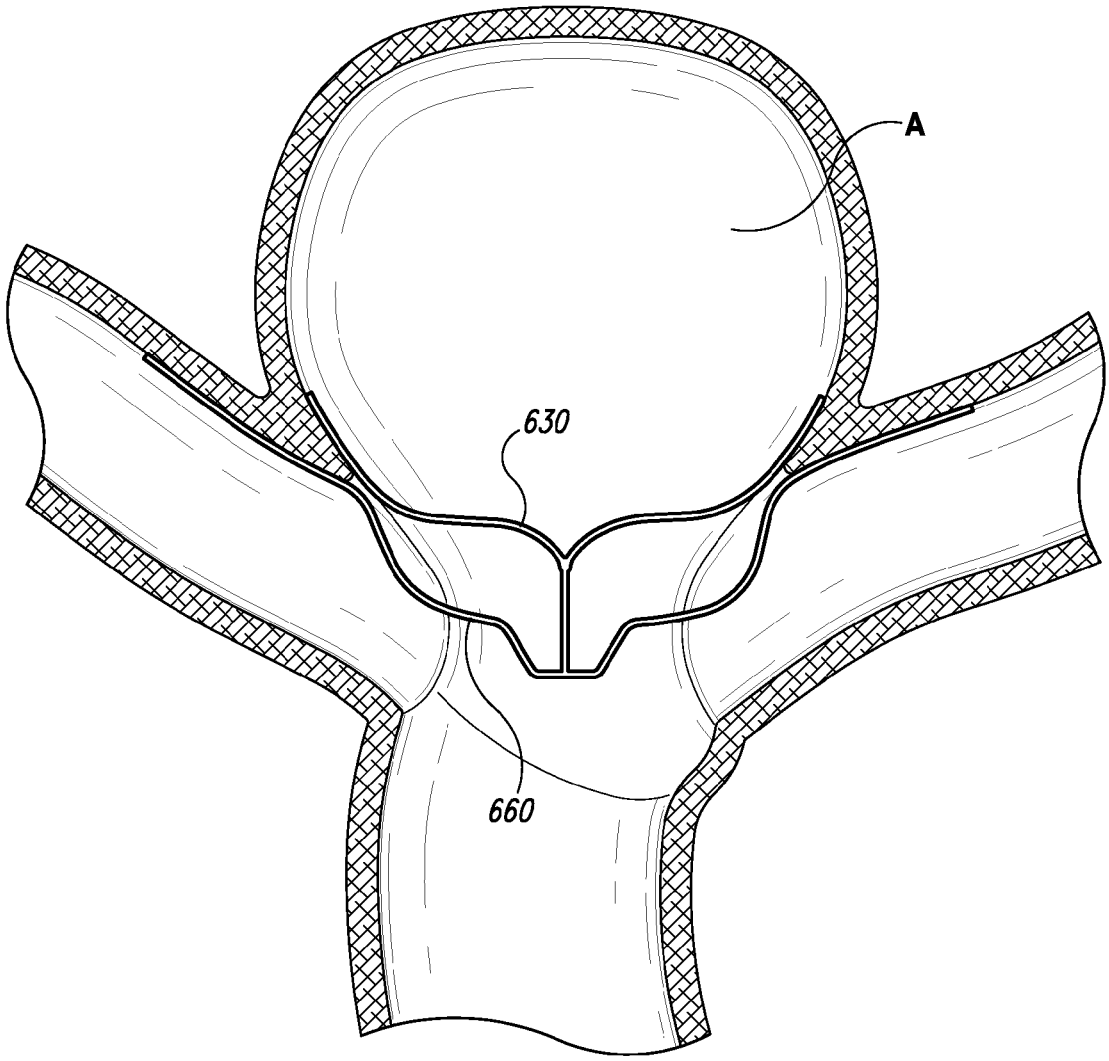


*Fig. 6C*

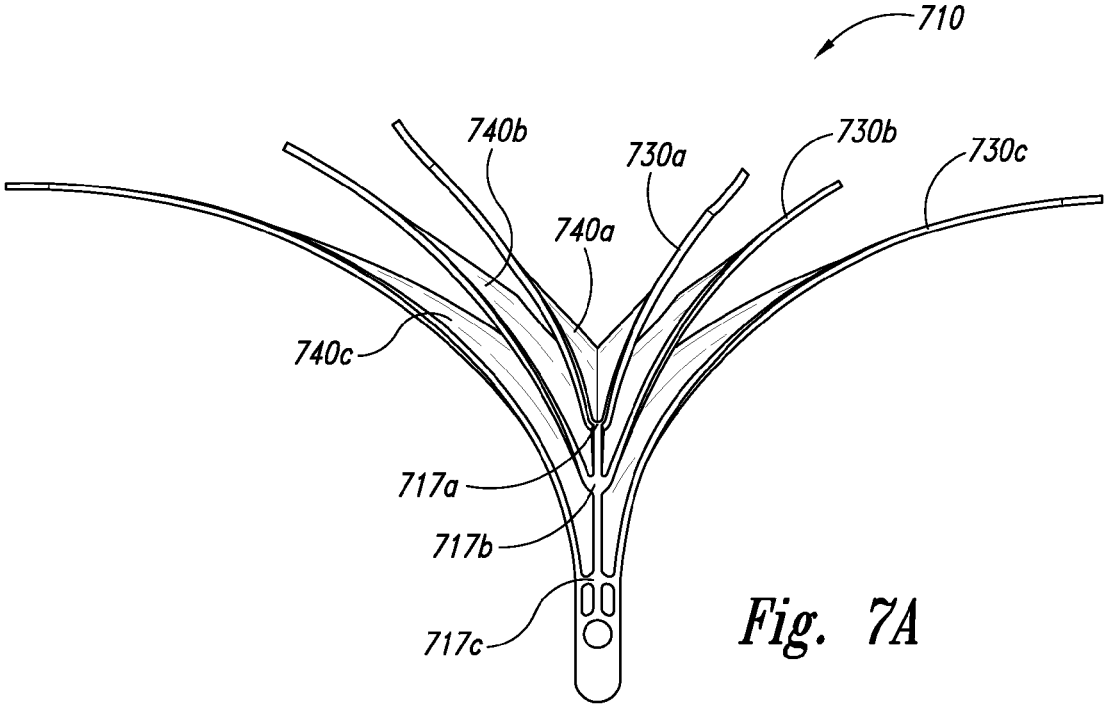
710
740b
730a
730b
730c
740a
740c
717a
717b
717c

Fig. 7A

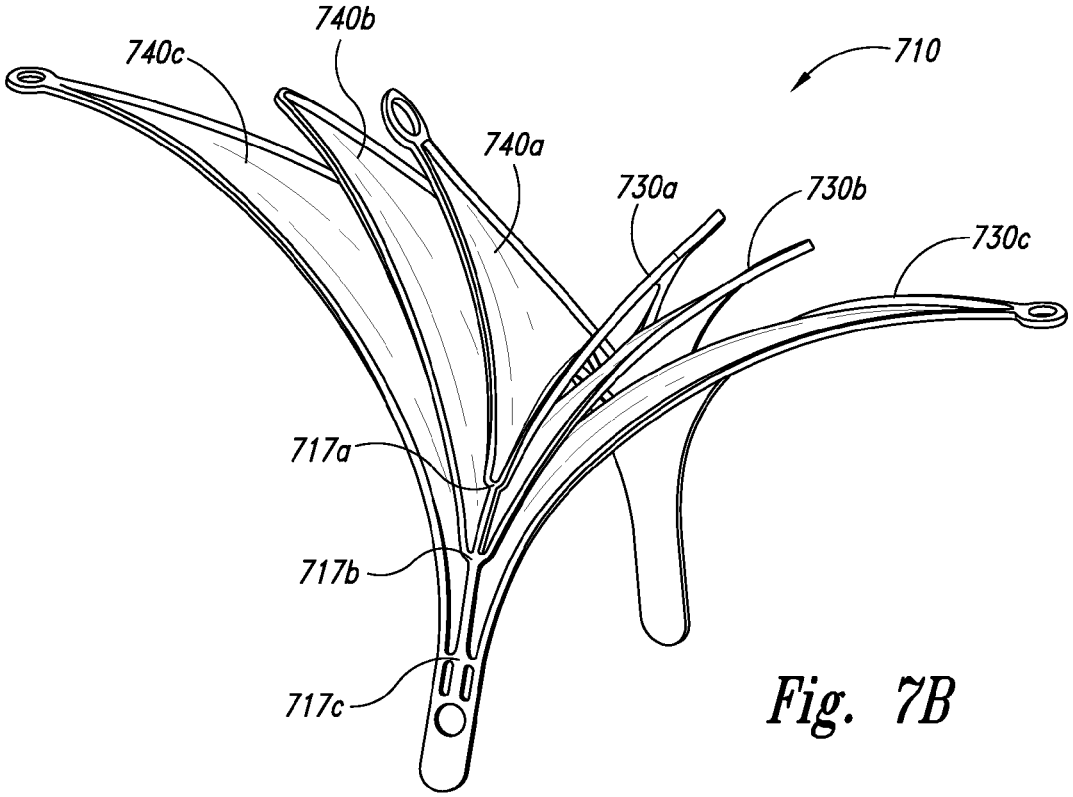
740b
740c
710
740a
730a
730b
730c
717a
717b
717c

Fig. 7B

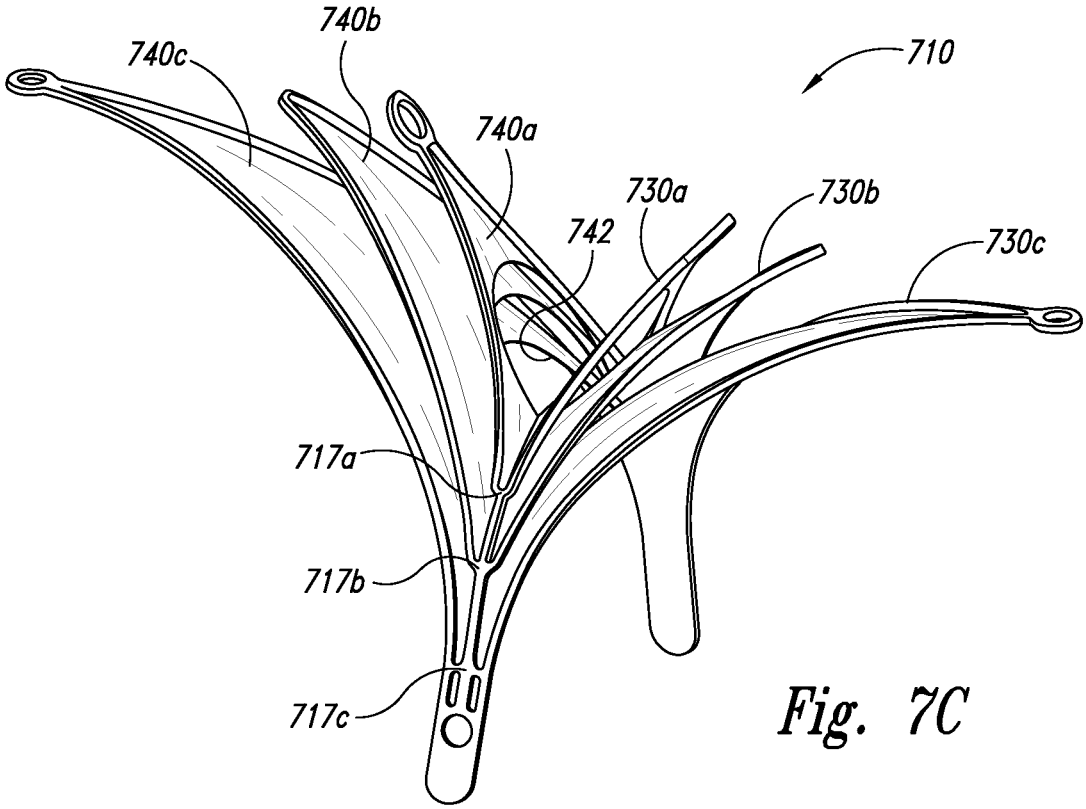
740b
740c
710
740a
730a
730b
742
730c
717a
717b
717c

Fig. 7C

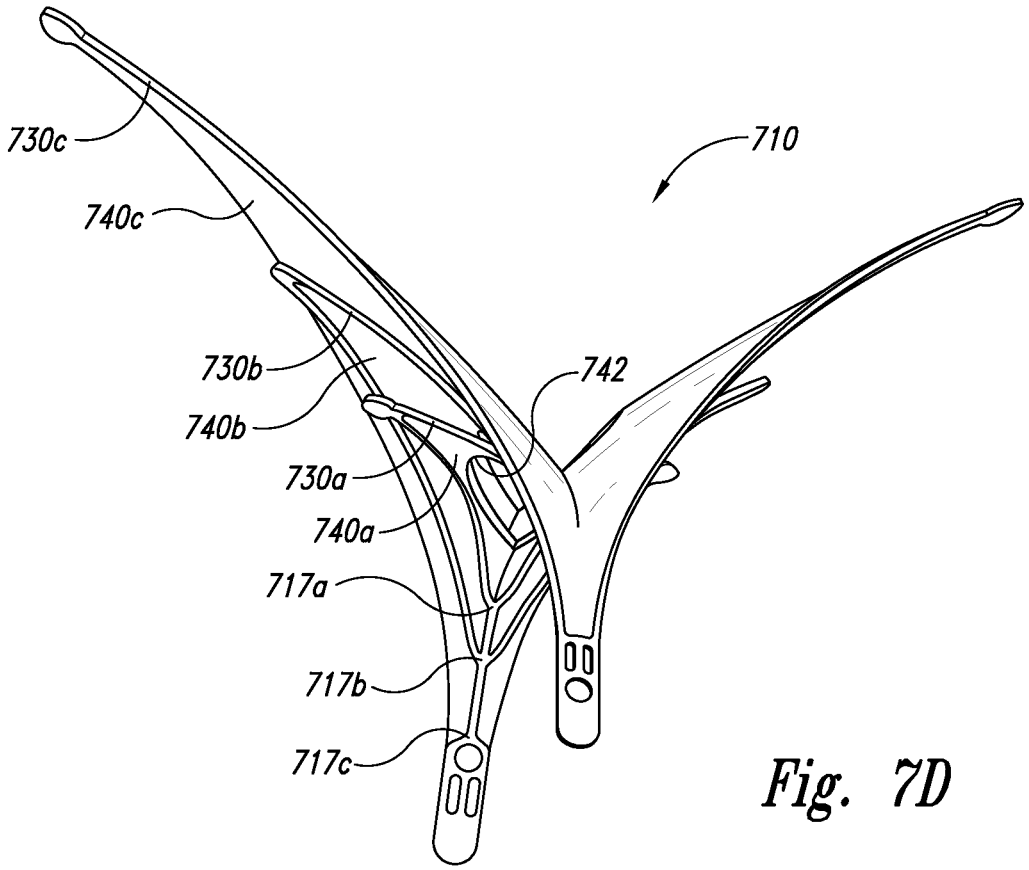
730c
710
740c
730b
742
740b
730a
740a
717a
717b
717c

Fig. 7D

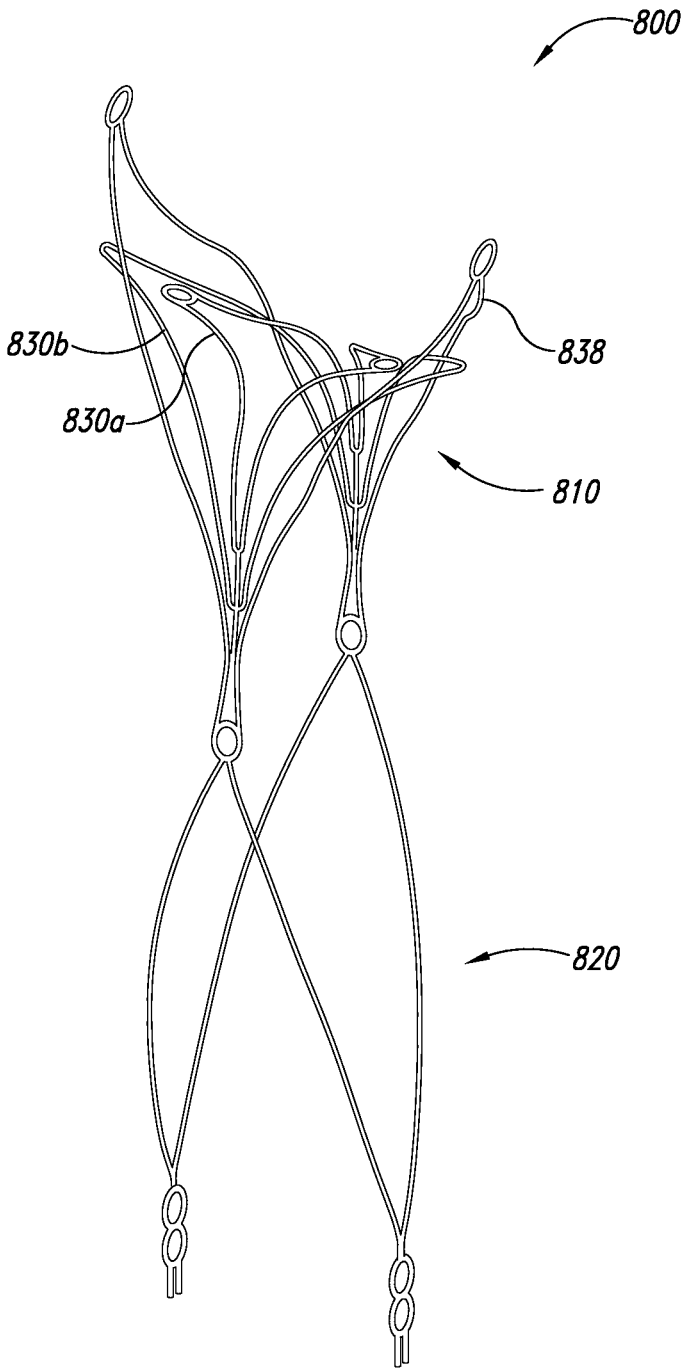


*Fig. 8A*

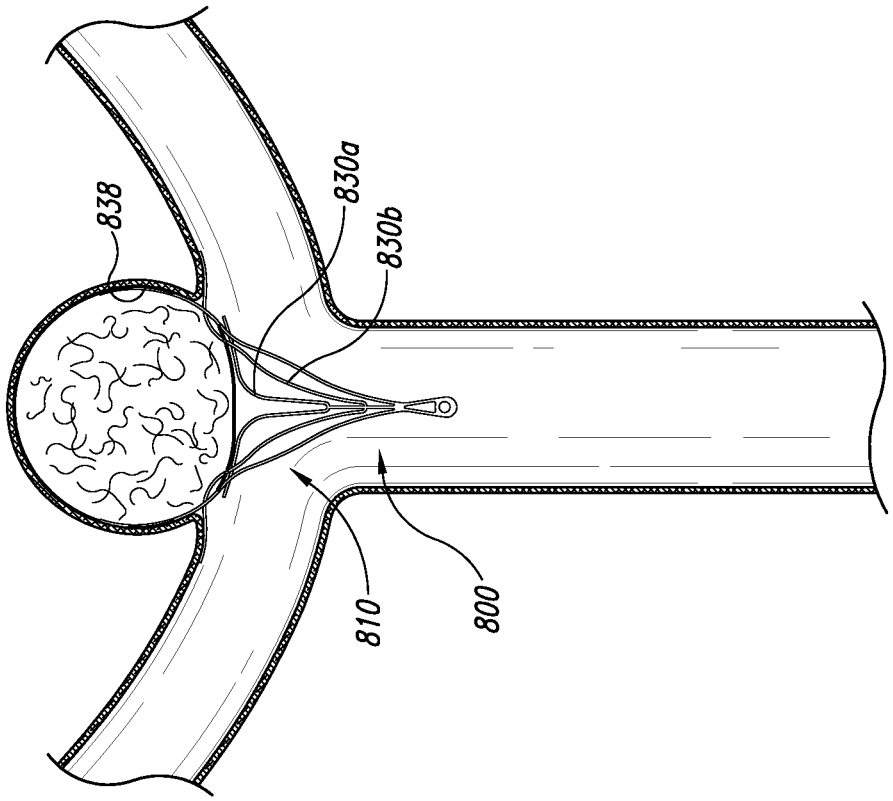


Fig. 8C

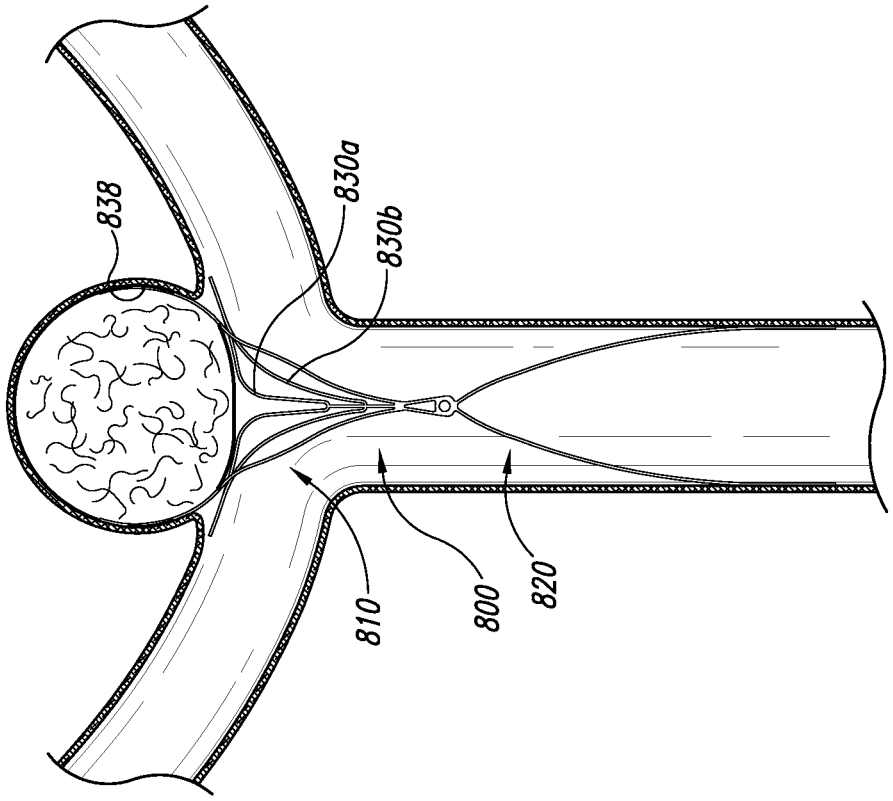


Fig. 8B

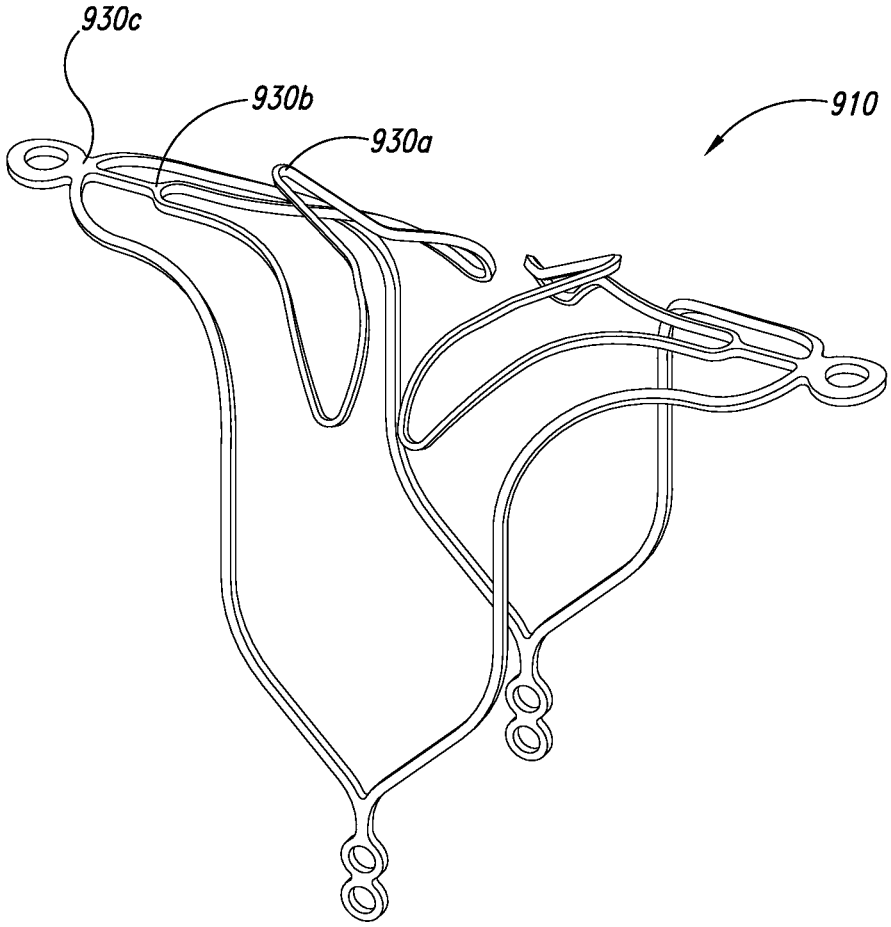


*Fig. 9*

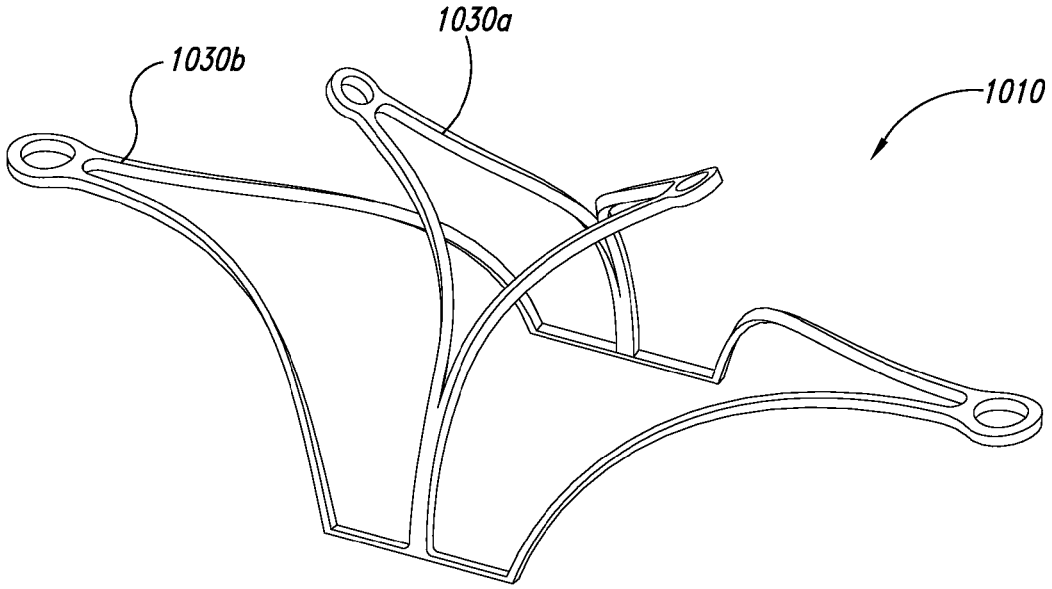


*Fig. 10A*

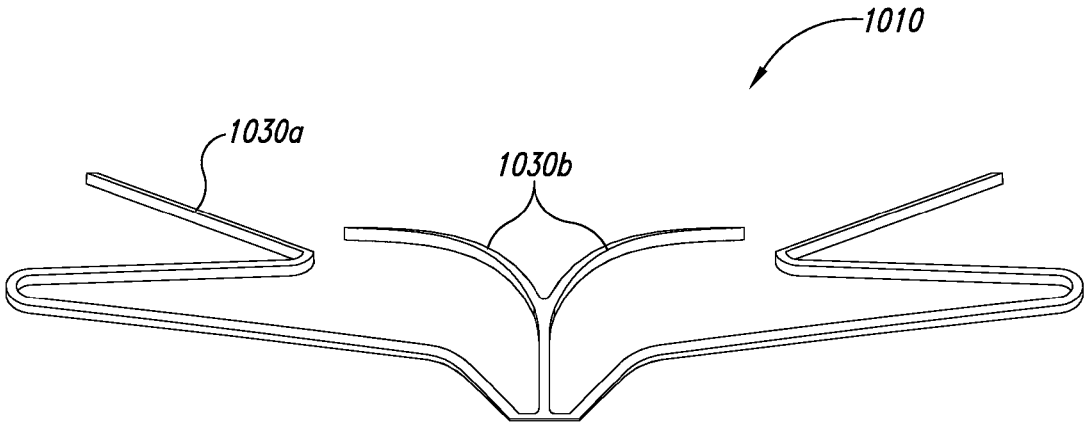


*Fig. 10B*

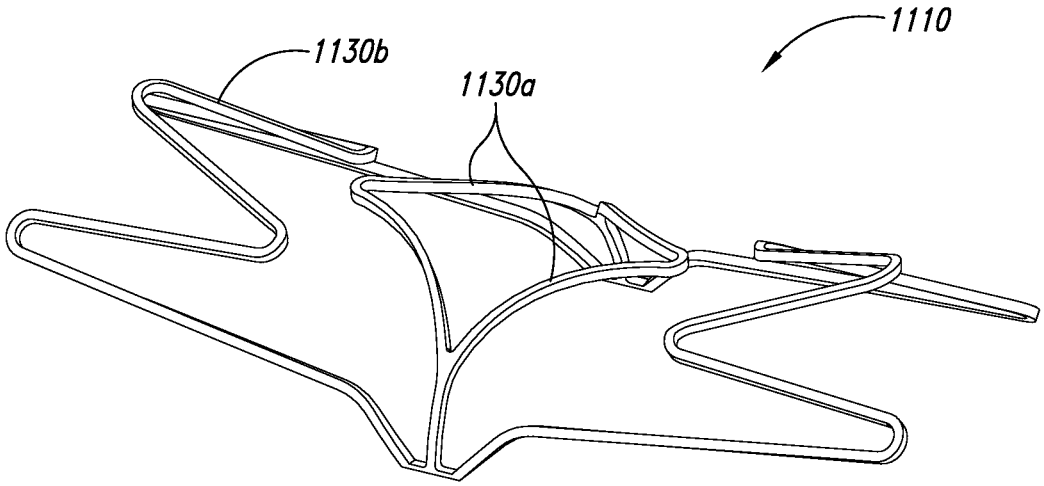


*Fig. 11A*

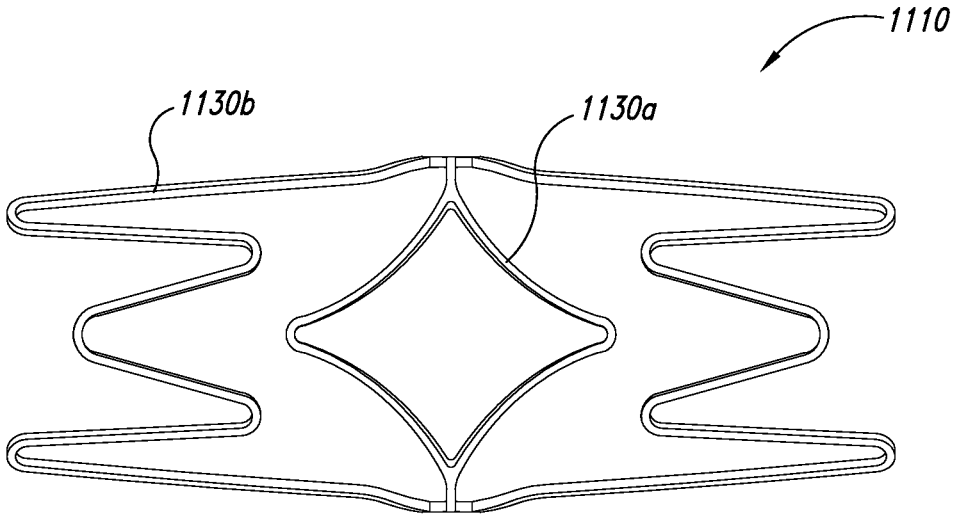


*Fig. 11B*

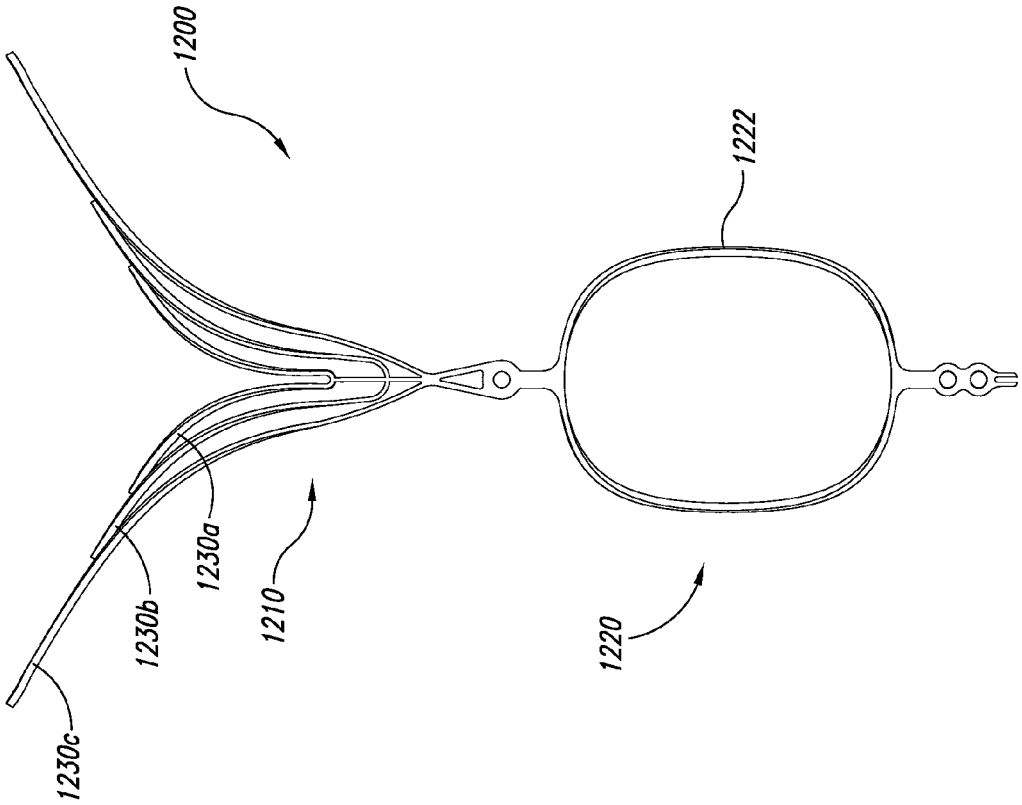


Fig. 12B

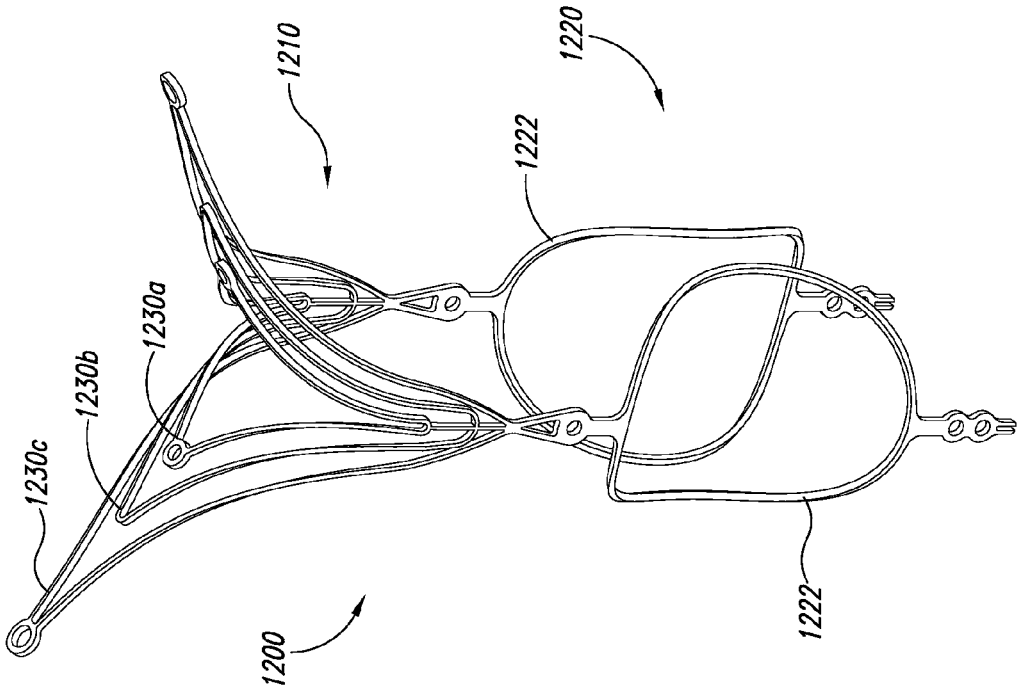


Fig. 12A

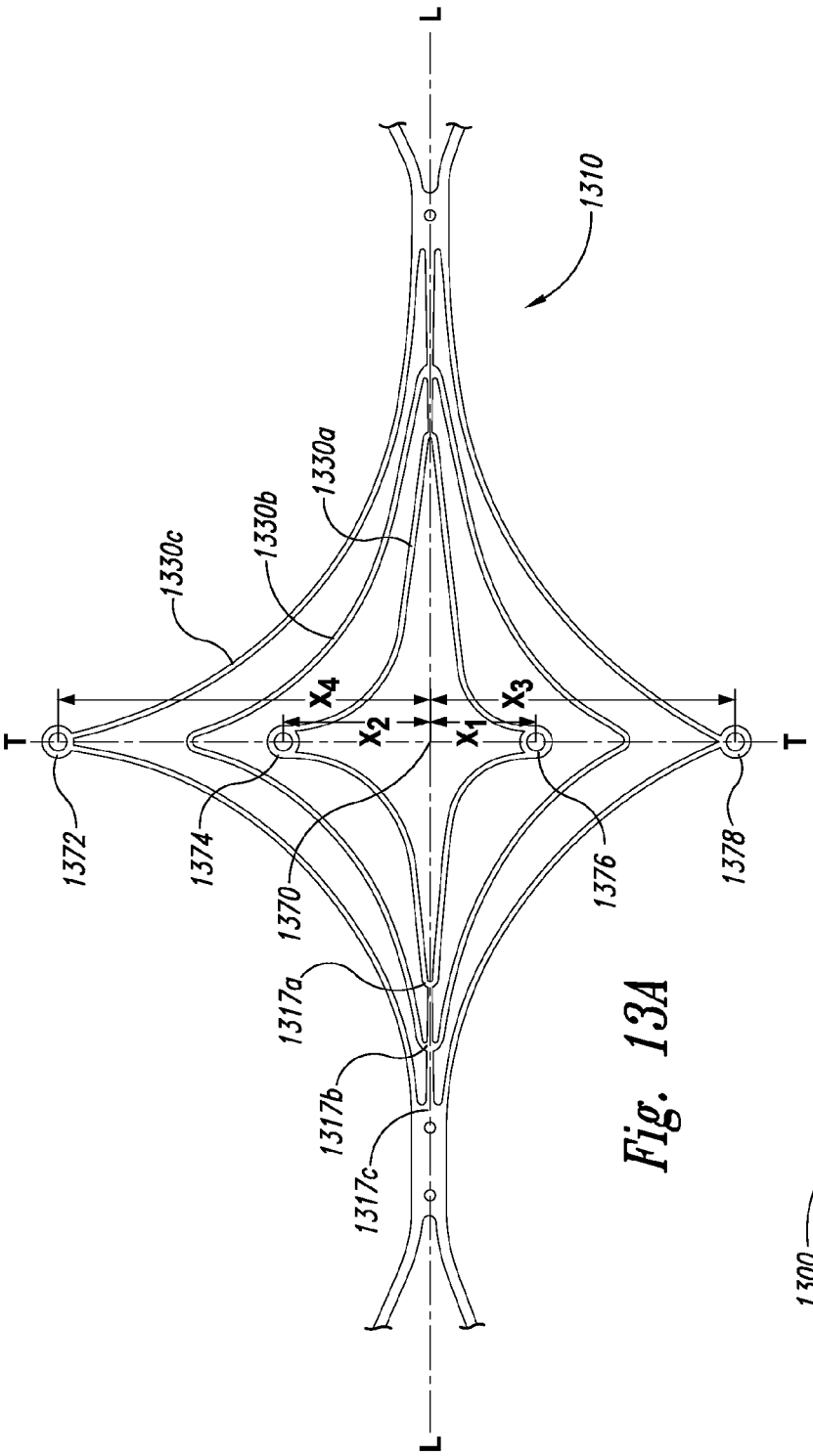


Fig. 13A

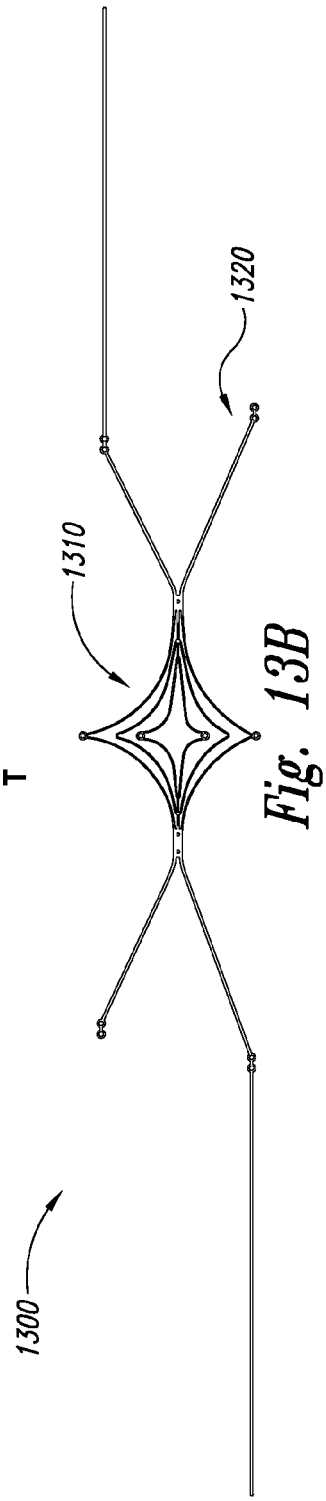


Fig. 13B

# DEVICES, SYSTEMS AND METHODS FOR ENCLOSING AN ANATOMICAL OPENING

## CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 61/543,785, filed Oct. 5, 2011, which is incorporated herein by reference in its entirety.

## TECHNICAL FIELD

The present technology relates to implantable therapeutic devices and methods for endovascular placement of devices at a target site, such as an opening at a neck of an aneurysm.

## BACKGROUND

Many of the currently available surgical approaches for closing openings and repairing defects in anatomical lumens and tissues (e.g., blood vessels), septal defects, and other types of anatomical irregularities and defects are highly invasive. Surgical methods for clipping brain aneurysms, for example, require opening the skull, cutting or removing overlying brain tissue, clipping and repairing the aneurysm from outside the blood vessel, and then reassembling tissue and closing the skull. Surgical techniques for repairing septal defects are also highly invasive. The risks related to anesthesia, bleeding, and infection associated with these types of procedures are high, and tissue that is affected during the procedure may or may not survive and continue functioning.

Minimally invasive surgical techniques have been developed to place occlusive devices within or across an opening or cavity in the body, such as in the vasculature, spinal column, fallopian tubes, bile ducts, bronchial and other air passageways, and the like. In general, an implantable device is guided along a delivery catheter and through a distal opening of the catheter using a pusher or delivery wire to deploy the device at a target site in the vasculature. Once the occlusive device has been deployed at the target site, it is detached from the pusher mechanism without disturbing placement of the occlusive device or damaging surrounding structures.

Minimally invasive techniques are also highly desirable for treating aneurysms. In general, the minimally invasive therapeutic objective is to prevent material that collects or forms in the cavity from entering the bloodstream and to prevent blood from entering and collecting in the aneurysm. This is often accomplished by introducing various materials and devices into the aneurysm. One class of embolic agents includes injectable fluids or suspensions, such as microfibrillar collagen, various polymeric beads, and polyvinylalcohol foam. Polymeric agents may also be cross-linked to extend their stability at the vascular site. These agents are typically deposited at a target site in the vasculature using a catheter to form a solid space-filling mass. Although some of these agents provide for excellent short-term occlusion, many are thought to allow vessel recanalization due to their absorption into the blood. Other materials, such as hog hair and suspensions of metal particles, have also been proposed and used to promote occlusion of aneurysms. Polymer resins, such as cyanoacrylates, are also employed as injectable vaso-occlusive materials. These resins are typically mixed with a radiopaque contrast material or are made radiopaque by the addition of a tantalum powder. Accurate and timely placement of these mixtures is crucial and very difficult because it is difficult or impossible to control them once they have been placed in the blood flow.



Implantable vaso-occlusive metallic structures are also well known and commonly used. Many conventional vaso-occlusive devices have helical coils constructed from a shape memory material or noble metal that forms a desired coil configuration upon exiting the distal end of a delivery catheter. The function of the coil is to fill the space formed by an anatomical defect and to facilitate the formation of an embolus with the associated allied tissue. Multiple coils of the same or different structures may be implanted serially in a single aneurysm or other vessel defect during a procedure. Implantable framework structures are also used in an attempt to stabilize the wall of the aneurysm or defect prior to insertion of filling material such as coils.

Techniques for delivering conventional metallic vaso-occlusive devices to a target site generally involve a delivery catheter and a detachment mechanism that detaches the devices, such as a coil, from a delivery mechanism after placement at the target site. For example, a microcatheter can be initially steered through the delivery catheter into or adjacent to the entrance of an aneurysm either with or without a steerable guidewire. If a guidewire is used, it is then withdrawn from the microcatheter lumen and replaced by the implantable vaso-occlusive coil. The vaso-occlusive coil is advanced through and out of the microcatheter and thus deposited within the aneurysm or other vessel abnormality. It is crucial to accurately implant such vaso-occlusive devices within the internal volume of a cavity and to maintain the device within the internal volume of the aneurysm. Migration or projection of a vaso-occlusive device from the cavity may interfere with blood flow or nearby physiological structures and poses a serious health risk.

In addition to the difficulties of delivering implantable occlusion devices, some types of aneurysms are challenging to treat because of structural features of the aneurysm or because of particularities of the site. Wide-neck aneurysms, for example, are known to present particular difficulty in the placement and retention of vaso-occlusive coils. Aneurysms at sites of vascular bifurcation are another example where the anatomical structure poses challenges to methods and devices that are effective in treating the typical sidewall aneurysms.

In view of such challenges, implanting conventional embolic coils, other structures, or materials in the internal space of an aneurysm has not been an entirely satisfactory surgical approach. The placement procedure may be arduous and lengthy because it often requires implanting multiple devices, such as coils, serially in the internal space of the aneurysm. Higher risks of complication from such sources as anesthesia, bleeding, thromboembolic events, procedural stroke, and infection are associated with such longer procedures. Moreover, because placement of structures in the internal space of an aneurysm does not generally completely occlude the opening, recanalization of the original aneurysm may occur, and debris and occlusive material may escape from within the aneurysm to create a risk of stroke or vessel blockage. Blood may also flow into the aneurysm and other blood vessel irregularities after the placement of embolic devices, which may increase the risks of complication and further enlargement of the aneurysm.

Despite the numerous conventional devices and systems available for implanting embolic materials in an aneurysm and for occluding physiological defects using minimally invasive techniques, these procedures remain risky and rarely restore the physiological structure to its normal, healthy condition. It is also challenging to position conventional implantable devices during deployment, prevent shifting or migration of such devices after deployment, and preserve blood flow in neighboring vessels following after deployment.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is an isometric view of an aneurysm device configured in accordance with an embodiment of the technology.

FIG. **1**B is an isometric view of a closure structure portion of the aneurysm device of FIG. **1**A.

FIG. **1**C is a front view of the aneurysm device of FIG. **1**A implanted at an aneurysm and configured in accordance with embodiments of the technology.

FIG. **2** is an isometric view of a closure structure portion of an aneurysm device configured in accordance with embodiments of the technology.

FIG. **3** is an isometric view of an aneurysm device configured in accordance with embodiments of the technology.

FIG. **4** is an isometric view of an aneurysm device configured in accordance with embodiments of the technology.

FIG. **5** is an isometric view of a closure structure portion of an aneurysm device configured in accordance with embodiments of the technology.

FIGS. **6**A and **6**B are isometric and front views, respectively, of a closure structure portion of an aneurysm device configured in accordance with embodiments of the technology.

FIG. **6**C is a front view of the closure structure portion of FIGS. **6**A and **6**B implanted at an aneurysm in accordance with embodiments of the technology.

FIG. **7**A is a front view of a closure structure portion of an aneurysm device configured in accordance with embodiments of the technology.

FIGS. **7**B-**7**D are isometric views of the closure structure portion of FIG. **7**A configured in accordance with embodiments of the technology.

FIG. **8**A is an isometric view of an aneurysm device configured in accordance with embodiments of the technology.

FIGS. **8**B and **8**C are front views of the aneurysm device of FIG. **8**A being placed at an aneurysm in accordance with embodiments of the technology.

FIG. **9** is an isometric view of a closure structure portion of an aneurysm device configured in accordance with embodiments of the technology.

FIGS. **10**A and **10**B are isometric and front views, respectively, of a closure structure portion of an aneurysm device configured in accordance with embodiments of the technology.

FIGS. **11**A and **11**B are isometric and top views, respectively, of a closure structure portion of an aneurysm device configured in accordance with embodiments of the technology.

FIGS. **12**A and **12**B are isometric and side views, respectively, of an aneurysm device configured in accordance with embodiments of the technology.

FIGS. **13**A and **13**B are top views an aneurysm device in an unassembled configuration in accordance with embodiments of the technology.

## DETAILED DESCRIPTION

The present disclosure describes implantable therapeutic devices and methods for endovascular placement of devices at a target site, such as an opening at a neck of an aneurysm. In several embodiments, a therapeutic aneurysm device is endovascularly deliverable to a site proximate to an arterial aneurysm. The aneurysm device comprises a closure structure having a distal-facing aspect configured to at least partially occlude the aneurysm and a proximal-facing aspect configured to arch over lumina of an artery. The device further includes a supplemental stabilizer connected to the closure structure and configured to reside in the artery and press outward against a luminal wall thereof. In some embodiments, the device can also include a barrier spanning at least a portion of the distal-facing aspect of the closure structure and configured to further occlude a neck of the aneurysm.

The following description provides specific details for a thorough understanding of, and enabling description for, embodiments of the disclosure. Well-known structures, systems, and methods often associated with aneurysm treatment have not been shown or described in detail to avoid unnecessarily obscuring the description of the various embodiments of the disclosure. In addition, those of ordinary skill in the relevant art will understand that additional embodiments may be practiced without several of the details described below.

FIG. **1**A is an isometric view of an aneurysm device **100** having a closure structure **110** and a support or supplemental stabilizer **120** configured in accordance with embodiments of the technology. FIG. **1**B is an isometric view of the closure structure **110**. Referring to FIGS. **1**A and **1**B together, the closure structure **110** can be a frame, scaffold, or other structure that at least partially occludes the neck of an aneurysm to prevent embolic coils or other coagulative material within the aneurysm from escaping into the bloodstream. The closure structure **110** comprises a plurality of scaffold struts or supports **130** (identified individually as struts **130***a*-**130***f*). The struts **130** are joined together at corners **115**, **116**, and **117**. The corners **115**, **116**, and **117** can be longitudinal corners that define the proximal end of the closure structure **110** that extends along the longitudinal axis L-L. The struts **130** can further include lateral corners **125**, **126**, and **127** defining a lateral aspect of the closure structure **110** that extends along the lateral axis T-T. The embodiment of the closure structure **110** illustrated in FIGS. **1**A and **1**B is generally symmetrical with respect to the centerlines of both the longitudinal L-L and the lateral T-T axes, but in other embodiments the closure structure **110** may have an asymmetrical configuration with respect to either or both of the longitudinal and lateral axes. Although the corners **125**, **126**, and **127** are illustrated as being rounded or looped, other embodiments of the corners may have a more pointed profile, a more complex curve, or other angular configurations. The struts **130** may be formed integrally with one another from a sheet of material, or separate struts may be formed and bonded together at the corners.

The closure structure **110** can define a distal framework portion, and the supplemental stabilizer **120** can define a proximal framework portion. Each of these portions can have one or more pairs of struts **130** (e.g., strut **130***a* is "paired" with strut **130***f*). In some embodiments, the struts **130** can curve inwardly toward the longitudinal axis L-L of the aneurysm device **100**. The outline of the struts **130** is typically that of a quadrilateral form. In some embodiments, the struts **130** can have a rhombus-like configuration or diamond shape. In several embodiments, the struts **130** can bend to provide a tailored fit to a particular vasculature. In some embodiments, the struts **130** can bend or flexibly move independently of one another. For example, strut **130***c* may bend further into an aneurysm body than strut **130***b*. This independent adjustability can provide a customized fit to the particular contours of a given aneurysm, creating a more secure hold.

As discussed above, the struts **130** can be symmetrical (e.g., the same length along orthogonal axes) or asymmetrical in which one side of the rhombus-like structure can have an axis longer than the other side. Although many closure structures **110** described below have quadrilateral forms, the closure structures **110** are not limited to these shapes in that the distal-facing aspect of the distal framework portion may have other shapes, such as polygons or polygonal curvilinear

shapes. In several embodiments, the rhombus-like supports **130** are concentric with a center at the longitudinal axis L-L of the aneurysm device **100**. The lateral apices of the closure structure **102** are disposed at opposing ends of the lateral axis T-T of the distal framework portion. The two portions of the distal framework portion opposite each other across the longitudinal axis L-L may define lateral leaves of the distal framework portion.

In various embodiments, the closure structure **110** can be used in combination with the supplemental stabilizer **120** or independently from the supplemental stabilizer **120** at a neck of an aneurysm. The laterally-extending branches of the closure structure **110** and the supplemental stabilizer **120** hold the curved portion of the closure structure **110** at the neck of the aneurysm. However, in some embodiments, using the closure structure **110** independently of the supplemental stabilizer **120** can decrease the amount of contact the aneurysm device **100** has with a patient's vasculature. For example, in some embodiments, the closure structure **110** can be used independently of the supplemental stabilizer in the treatment of a ruptured aneurysm. In some embodiments, the supplemental stabilizer **120** can be used during placement of the closure structure **110**, but then removed.

FIG. **1**C is a front view of the aneurysm device of FIG. **1**A in a deployed configuration and implanted at an aneurysm in accordance with embodiments of the technology. In the deployed configuration, the closure structure **110** has a distally projecting arch defined by a curved section of the distal framework portion. The supplemental stabilizer **120** extends proximally from the closure structure **110** at an angle relative to a lateral axis. A proximal-facing aspect of the arch of the closure structure **110** extends over the lumina of the bifurcating arteries. A distal-facing aspect of the arch of the closure structure **110** generally presses against the luminal surfaces of the bifurcating arteries. The distal-facing aspect of the closure structure **110** is configured to substantially align with or otherwise conform to the neck of the aneurysm by forming a curved surface that compatibly aligns with or engages the neck and the surrounding wall of the side branch vessels. In some embodiments, the distal-facing aspect has a complex curve, such as a hyperbolic paraboloid (e.g., a generally saddle-shaped form). In the illustrated embodiment, the hyperbolic paraboloid comprises a generally Y-shaped curve with a depressed central portion. The supplemental stabilizer **120** can have struts that extend down into the parent artery and press outwardly against the luminal surface thereof.

The distal-facing aspect or back of the proximal-facing surface generally aligns against the luminal surfaces of the bifurcating arteries, the sides of the arch extending down into the parent artery and aligned against the luminal surface thereof. The proximal face of the arch is generally and substantially transverse (perpendicular or orthogonal) to the lateral axis of the proximal framework. The arch spans unobtrusively over the lumina of the bifurcating arteries, forming no incursion into the vascular flow path. More particularly, the arch can be a non-enclosed opening or hole, but instead a structure entirely open in the proximal direction. In further embodiments, as will be discussed in more detail below, the closure structure **110** can include a cover or barrier portion spanning across one or more distal framework struts and configured to occlude the neck of the aneurysm.

FIG. **2** is an isometric view of a closure structure **210** of an aneurysm device configured in accordance with embodiments of the technology. The closure structure **210** has several features generally similar to the closure structure **110** described above with reference to FIGS. **1**A-**1**C. The closure structure **210** further includes a barrier **240** spanning across a distal-facing aspect.

In the illustrated embodiment, the closure structure **210** includes perimeter struts **232** and curved inner arms **230** that meet the perimeter struts **232** at longitudinal corner points **217**. The closure structure **210** is capable of temporary or permanent attachment to a supplemental stabilizer (such as the supplemental stabilizer **120** described above with reference to FIG. **1**A) at the corner points **217**. The inner arms **232** extend distally from the corner point **217**, along a longitudinal midline L-L of the closure structure **210**, and curve distally and laterally to an off-centered position. The inner arms **232** therefore allow the closure structure **210** and the barrier **240** to keep and maintain a shape in a deployed configuration and to fold up or compress in a spiral manner during delivery and/or removal.

The barrier **240** can be formed with or permanently or removably attached to the perimeter and inner arms **232**, **230**. The barrier **240** can comprise one or more permeable or semi-permeable membranes, covers, sheets, panels, mesh, or other structures that form an occlusive or semi-occlusive covering that (a) restricts, diverts, redirects, or inhibits vascular flow into the cavity of the aneurysm and/or (b) prevents materials from escaping the cavity. In this aspect, devices and methods of the described technology may provide repair and reconstruction of a blood vessel or a junction of blood vessels by placement and retention of the closure structure **210** across the neck of the aneurysm that diverts blood flow away from the aneurysm. Following placement and deployment, the barrier **240** may substantially cover the aneurysm neck and the closure structure **210** can form a structure that substantially conforms to the tissue surrounding the aneurysm and/or the neighboring vessel walls. The highly conforming fit generally restores the vascular anatomical neighborhood to a normal or more normal configuration, thereby supporting a normal vascular flow pattern and overall function. In the illustrated embodiments, the barrier **240** includes a barrier aperture **242** configured to provide access to the aneurysm (e.g., access for a catheter, access to deliver coils, etc.) As will be described in further detail below, the barrier **240** can comprise a single sheet or panel, or can comprise a plurality of sheets or panels layered and/or otherwise arranged on the device to achieve a desired barrier pattern and/or structure.

FIG. **3** is an isometric view of an aneurysm device **300** configured in accordance with embodiments of the technology. Generally similar to the aneurysm devices described above, the aneurysm device **300** includes a closure structure **310** and a supplemental stabilizer **320**. The closure structure **310** comprises a plurality of nested, rhombus-shaped pairs of struts **330***a*-**330***c* (collectively struts, **330**). A barrier **340** spans the struts **330** and includes a central hole or slit **342** at a central portion of the closure structure **310**, within the innermost set of struts **330***a*.

FIG. **4** is an isometric view of an aneurysm device **400** configured in accordance with embodiments of the technology. Generally similar to the aneurysm device **300** described above with reference to FIG. **3**, the aneurysm device **400** includes a closure structure **410** and a supplemental stabilizer **420**. The closure structure **410** comprises a plurality struts **430***a*-**430***c* (collectively struts, **430**) forming nested rhombus shapes. In this embodiment, however, a barrier **440** spans only the space between the innermost struts **330***a* and the middle struts **330***b*.

The illustrated configurations are merely representative of the numerous arrangements the struts **430** and barrier **440** could take. For example, there could be more or fewer than

three sets of nested struts **430**, and the barrier **440** could cover more or fewer areas or parts of areas between the struts **430**. In some embodiments, the degree of barrier coverage across the struts can be selected based on a desired degree of occlusion, type or characteristics of the aneurysm, and/or desired access to the body of the aneurysm.

FIG. **5** is an isometric view of a closure structure portion **510** of an aneurysm device configured in accordance with embodiments of the technology. The closure structure **510** has several features generally similar to the closure structure **210** described above with reference to FIG. **2**. For example, the closure structure **510** has a barrier **540** spanning across perimeter struts **532** and curved inner arms **530**. the barrier **540** includes an optional access aperture **542**.

The closure structure **510** further includes flexible anchor legs **552** distally coupled to the perimeter struts **530**. While two legs **552** are shown descending from the illustrated side of the closure structure **510**, there can be more or fewer legs **552**, of the same or different dimensions, in further embodiments of the technology. The anchor legs **552** can provide pivotable movement (or shock absorption) between the closure structure **610** and a supplemental stabilizer, such as the supplemental stabilizer **120** described above with reference to FIG. **1**A. The anchor legs **552** can comprise springs, hinges, or other movable or flexible structures that would allow movement of the closure structure **510** relative to a supplemental stabilizer.

FIGS. **6**A and **6**B are isometric and front views, respectively, of a closure structure **610** having several features generally similar to the closure structures described above. FIG. **6**C is a front view of the closure structure **610** at an aneurysm in accordance with embodiments of the technology. Referring to FIGS. **6**A-**6**C together, the closure structure **610** includes a barrier **640** spanning distal arms **630**. The closure structure **610** further includes proximal arms **660** coupled to the distal arms **630** via a midline strut **662**. In the illustrated embodiment, the midline strut **662** extends distally from a distal arm junction point **617**. The barrier **640** can include an aperture **642** therein.

In several embodiments, at least one of the distal arms **630** or proximal arms **660** are curved or parabolic shaped to better conform to the shape of the aneurysm or the vasculature to provide the desired degree of aneurysm occlusion and device stability. For example, in the illustrated embodiment, the distal arms **630** extend distally but have a lateral, proximally-dipping curve, while the proximal arms **660** have an approximately 180-degree distal curve before projecting laterally. As best shown in FIG. **6**C, the distal arms **630** can be placed within the aneurysm and can conform against the aneurysm wall, while the proximal arms **660** can conform against the luminal wall outside of the aneurysm.

FIG. **7**A is a front view of a closure structure **710** configured in accordance with embodiments of the technology. FIGS. **7**B-**7**D are isometric views of the closure structure **710**. Referring to FIGS. **7**A to **7**D together, the closure structure **710** includes multiple sets of nested, generally triangular-shaped baffles or panels **730***a*-**730***c* (collectively panels **730**). Each panel **730** comprises a strut framework and sheets or panels of barrier **740***a*-**740***c* (collectively barrier **740**). Pairs of panels **730** join at junctions **717***a*-**717***c* on a central stem.

The panels **730** can be individually covered by the barrier **740**, or pairs of struts (e.g., forming a V-shape) can be covered. One or more panels **730** can include an opening or hole **742**. For example, in the illustrated embodiment, the closure structure **710** includes a central hole **742** that extends longitudinally through each pair of adjacent panels **730**, thereby providing access from a proximal side of the closure structure **710** to the interior of the aneurysm. While the panels **730** are discussed as triangles, in further embodiments the panels **730** can be shaped as rectangles, circles, squares, or other polygonal or curved shapes. The panels **730** can laterally overlap and can be used to control, contain, and/or divert flow. The panels **730** can function as baffles that can pivotably bend or otherwise move relative to one another to adjust from an open state to a closed state. In various embodiments of use, one or more of the panels **730** can be inside the aneurysm while other panels **730** can be outside the aneurysm. In further embodiments, all of the panels **730** can be inside or outside the aneurysm.

FIG. **8**A is an isometric view of an aneurysm device **800** configured in accordance with embodiments of the technology. The aneurysm device **800** includes a closure structure **810** and a supplemental stabilizer **820**. The closure structure **810** includes one or more rhombus-shaped sets of struts **830***a*, **830***b* (collectively struts **830**), generally similar to the closure structures described above. The closure structure **810** further includes distally-extending anchor arms **838**. In the illustrated embodiment, the struts **830** are curved distally and laterally, in some embodiments extending laterally beyond the anchor arms **838**.

FIGS. **8**B and **8**C are front views of the aneurysm device of FIG. **8**A being placed at an aneurysm in accordance with embodiments of the technology. The struts **830** are configured to curve against the exterior neck of the aneurysm. In further embodiments, one or more of the struts **830** can be placed within the aneurysm. The anchor struts **838** can be located within the side walls of the aneurysm and can provide improved fit/conformability to the aneurysm neck. As shown in FIG. **8**C, in some embodiments, the supplemental stabilizer **820** can be removed upon stable placement of the closure structure **810** or can be not used at all.

FIG. **9** is an isometric view of a closure structure portion **910** of an aneurysm device configured in accordance with further embodiments of the technology. Having features generally similar to several of the closure structures described above, the closure structure **910** includes inner, middle, and outer sets of struts (numbered **930***a*-**930***c*, respectively). In the illustrated embodiment, the inner struts **930***a* expand or bend distally upward from the laterally-joined middle and outer struts **903***b*, **903***c*. This bendability provides a niche between the inner **930***a* and middle **930***b* struts. In use, the niche can be used to clip into or otherwise engage the tissue proximate to the aneurysm.

FIGS. **10**A and **10**B are isometric and front views, respectively, of a closure structure **1010** configured in accordance with embodiments of the technology. The closure structure **1010** includes an inner set of struts **1030***a* and an outer set of struts **1030***b*. In some embodiments, the inner set of struts **1030***a* can be bent or formed in a direction offset from the outer set of struts **1030***b* to "expand" the aneurysm device **300**. In some embodiments, the inner set of struts **1030***a* can be placed in an aneurysm and the outer set of struts **330***b* can be placed outside the aneurysm to anchor or stabilize the closure structure **1010** (e.g., to clip the aneurysm device into the aneurysm).

FIGS. **11**A and **11**B are isometric and top views, respectively, of a closure structure **1110** configured in accordance with embodiments of the technology. The closure structure **1110** includes an inner set of struts **1130***a* and an outer set of struts **1130***b*. In some embodiments, the inner set of struts **1130***a* can be bent or formed in a direction offset from the outer set of struts **1130***b*. In some embodiments, the inner set of struts **1130***a* can be placed in an aneurysm and the outer set

of struts **1130***b* can be placed outside the aneurysm for anchoring the closure structure **1110**.

FIGS. **12**A and **12**B are isometric and side views, respectively, of an aneurysm device **1200** configured in accordance with embodiments of the technology. The aneurysm device **1200** includes a closure structure **1210** and a supplemental stabilizer **1220**. The closure structure **1210** includes sets of struts **1230***a*-**1230***c* (collectively, struts **1230**) arranged in triangular or rhombus configurations and extending laterally from a midline of the device **1200**. As described in several embodiments above, the sets of struts **1230** can rest in or outside an aneurysm, or can sandwich or clip onto the neck of the aneurysm. In the illustrated embodiment, the supplemental stabilizer **1220** includes ring-shaped anchors **1222** extending proximally from the closure structure **1210**. These anchors **1222** can be configured to press against vascular walls to provide device stability without blocking blood flow.

FIGS. **13**A and **13**B are top views an aneurysm device **1300** in an unassembled configuration in accordance with embodiments of the technology. Referring to FIGS. **13**A and **13**B together, the aneurysm device **1300** is constructed from a substantially flat substrate by cutting, etching, stamping, or otherwise forming the framework of the closure structure **1310** and the unassembled supplemental stabilizer **1320**. In several embodiments, the device **1300** can be cut from a single piece of substrate. For example, the closure structure **1310** (including sets of struts **1330***a*-**1330***c*) and the supplemental stabilizer **1320** can be constructed from a flat sheet of material having substantially uniform thickness. In other embodiments different regions of the sheeted material can have different thicknesses corresponding to the desired thickness for portions of the closure structure **1310** and/or the supplemental stabilizer **1320**.

The closure structure **1310** can be folded or bent into a curve along the lateral axis T-T such that the portions of the closure structure **1310** associated with corners **1317***a*-**1317***c* define paired longitudinally aligned structures on either side and generally substantially orthogonal to the lateral axis T-T. The paired longitudinally aligned structures can be substantially parallel to each other and define anchors that hold the closure structure **1310** in place. The closure structure **1310** forms a vertex that is resiliently bent by a total of about 180° and is biased outward. The outward bias of the closure structure **1310** is due to the materials that form the closure structure, such as resilient metals or alloys including Nitinol and other shape memory metals. The outward biasing force is conveyed to the supplemental stabilizer **1320** from the closure structure **1310** such that the supplemental stabilizer **1320** presses outward against the lumen of a parent vessel that extends at an angle relative to the lengthwise dimension of the closure structure **1310**.

Radiopaque markers **1372**, **1374**, **1376**, and **1378** or radiopaque compounds may be associated with certain structures or portions of the device structure to facilitate accurate positioning, placement and monitoring of the deployed device in the vasculature. In one embodiment, for example, a radiopaque composition may be incorporated in the closure structure or provided as a coating on the closure structure. Variations in the marker geometry may be adopted to distinguish different segments of the device framework. For example, the proximal legs of the device may incorporate a marker with two dots, while the portion of the device closer to or in proximity to the covering may incorporate a single dot. Alternatively, different shaped markers may be used to differentiate different parts of the device. Radiopaque markers may be added anywhere along the device frame or attached materials, coverings, and membranes to provide spatial location of different device components and features under angiography. In several embodiments, for example, radiopaque markers can be added to laterally and/or longitudinally asymmetric points on the closure structure **1310** and/or supplemental stabilizer **1320** (i.e., asymmetric with reference to the lateral axis T-T, longitudinal axis L-L, or a center point **1370** at the intersection of the longitudinal and lateral axes). In the embodiment illustrated in FIG. **13**A, markers **1372**, **1374**, **1376**, and **1378** are offset from the longitudinal axis L-L. Marker **1372** is offset by distance $X_4$, marker **1374** is offset by distance $X_2$, marker **1376** is offset by distance $X_1$, and marker **1378** is offset by distance $X_3$, where $X_1$, $X_2$, $X_3$, and $X_4$ are all unequal distances. By placing these markers asymmetrically, the markers do not overlap when the device is folded or compressed during placement. The device **1300** is therefore less bulky for delivery.

From the foregoing, it will be appreciated that specific embodiments of the disclosure have been described herein for purposes of illustration, but that various modifications may be made without deviating from the spirit and scope of the disclosure. For example, structures (such as supplemental stabilizers and/or barriers) and/or processes described in the context of particular embodiments may be combined or eliminated in other embodiments. In particular, the aneurysm devices described above with reference to particular embodiments can include one or more additional features or components, or one or more of the features described above can be omitted. Moreover, while advantages associated with certain embodiments of the disclosure have been described in the context of these embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the disclosure.

We claim:

**1**. An aneurysm device endovascularly deliverable to a site proximate to an aneurysm, the aneurysm device comprising:

an arched closure structure comprising a distal-facing aspect configured to at least partially occlude the aneurysm, and a proximal-facing aspect configured to arch over lumina of an artery, wherein the arch is configured to span unobtrusively over the lumina and forms no incursion into the vascular flow path;

a supplemental stabilizer connected to the closure structure, the supplemental stabilizer configured to reside in the artery and press outward against a luminal wall thereof; and

a barrier spanning at least a portion of the distal-facing aspect of the closure structure, the barrier having an aperture therein configured to provide access to the aneurysm, wherein the aperture is sized and shaped to allow passage of a catheter therethrough.

**2**. The aneurysm device of claim **1** wherein the barrier comprises a permeable or semi-permeable membrane configured to restrict or inhibit flow to or from the aneurysm.

**3**. The aneurysm device of claim **1** wherein the barrier comprises overlapping layers of sheets or panels.

**4**. The aneurysm device of claim **1** wherein the closure structure comprises a plurality of laterally opposing supports, each support individually-covered with a barrier material having an aperture therein.

**5**. The aneurysm device of claim **1** wherein the distal-facing aspect of the closure structure and the barrier form a complex curved surface.

**6**. The aneurysm device of claim **5** wherein the complex curved surface comprises a hyperbolic paraboloid form.

**7**. The aneurysm device of claim **1** wherein the closure structure comprises three sets of laterally opposing supports,

the supports comprising inner, middle, and outer supports, and wherein the barrier material extends exclusively between the inner and middle supports.

**8**. The aneurysm device of claim **1** wherein the closure structure, supplemental stabilizer, and aperture comprise a longitudinal axis of the device.

**9**. An aneurysm device endovascularly deliverable to a site proximate to an aneurysm, the aneurysm device comprising:

a closure structure comprising a distal-facing aspect configured to at least partially occlude the aneurysm, and a proximal-facing aspect configured to arch over lumina of an artery;

a supplemental stabilizer connected to the closure structure, the supplemental stabilizer configured to reside in the artery and press outward against a luminal wall thereof; and

a barrier spanning at least a portion of the distal-facing aspect of the closure structure, the barrier having an aperture therein configured to provide access to the aneurysm,

wherein the closure structure further comprises three sets of laterally opposing supports, the supports comprising inner, middle, and outer supports, and wherein the barrier extends exclusively between the inner and middle supports.

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UNITED STATES PATENT AND TRADEMARK OFFICE

# CERTIFICATE OF CORRECTION



PATENT NO. : 9,119,625 B2
APPLICATION NO. : 13/646602
DATED : September 1, 2015
INVENTOR(S) : Bachman et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, in item (56), in column 2, under "Other Publications", line 1, delete "Polytetraflouroethylene" and insert -- Polytetrafluoroethylene --, therefor.

On the title page, in item (56), in column 2, under "Other Publications", line 2, delete "dermetnz.org" and insert -- dermnetnz.org --, therefor.

On the page 3, in column 2, under "Other Publications", line 10, delete "Copr.; "Concurse" and insert -- Corp.; "Concours --, therefor.

On the page 3, in column 2, under "Other Publications", line 14, delete ""Prolwer" and insert -- "Prowler --, therefor.

In column 7, line 13, delete "the barrier" and insert -- The barrier --, therefor.

Signed and Sealed this
Fifth Day of July, 2016

Michelle K. Lee

Michelle K. Lee
*Director of the United States Patent and Trademark Office*